

REMARKS

This responds to the non-final Office Action dated 25 September 2007. Claims 1, 5, 20, 28, 45, 46, 47, 48, and 55 have been amended and claims 17 and 19 have been cancelled. Support for these amendments can be found variously throughout the specification, including, for example, original claims 1, 5, 17, 19, 20, and 28, page 4, lines 7-22, and FIGS. 4-6. No new matter has been added. Accordingly, claims 1, 4, 5, 7, 12-16, 20-22, 24, 25, 28-39, and 45-60 are presently pending in the application, each of which Applicants believe is in condition for allowance. Applicants respectfully request reconsideration of the application in light of the above amendments and the following remarks.

For simplicity and clarity purposes in responding to the Office Action, Applicants' remarks are primarily focused on the rejections applied to the independent claims (*i.e.*, claims 1, 28, 45, 46, 47, and 48) as outlined in the Office Action with the understanding that the dependent claims are patentable for at least the same reasons (and in most cases other reasons) that the independent claims are patentable. Applicant expressly reserves the right to argue the patentability of the dependent claims separately in any future proceedings.

Claim Rejections – 35 U.S.C. § 102

In the Action, the Examiner rejected claims 1, 4, 5, 7, 12-17, 19-21, 28-39, and 45-60 under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent No. 6,626,918 to Ginn et al. ("Ginn"). The Examiner also rejected claims 48-60 under 35 U.S.C. § 102(b) as allegedly

being anticipated by U.S. Patent No. 6,179,863 to Kensey et al. ("Kensey"). Applicants respectfully traverse this rejection.

Independent claim 1 of the present application recites, *inter alia*, "an insertion sheath; a dilator sized to fit inside the insertion sheath, the dilator having a distal end positionable distally beyond a distal end of the insertion sheath; a first distal hole located in the distal end of the dilator" and "a second distal hole located in the distal end of the insertion sheath." Similarly, independent claim 28 of the present application recites, *inter alia*, "an insertion sheath having a distal end and a proximate end; a dilator having a distal end and a proximate end, the dilator being sized to fit in the insertion sheath, the distal end of the dilator positionable distally beyond the distal end of the insertion sheath; a first distal hole located in the distal end of the dilator" and "a second distal hole located in the distal end of the insertion sheath." In addition, independent claims 45 and 46 recite, *inter alia*, "an insertion sheath, wherein the second distal hole is located in the insertion sheath" and "a dilator sized to fit inside the insertion sheath, the dilator having a distal end positionable distally beyond a distal end of the insertion sheath, wherein the first distal hole is located in the distal end of the dilator." Independent claim 47 recites, *inter alia*, "an insertion sheath having a distal end and a proximate end; a dilator sized to fit inside the insertion sheath, the dilator having a distal end and a proximate end, the distal end of the dilator positionable distally beyond the distal end of the insertion sheath; a first inlet port located in the distal end of the dilator" and "a second inlet port in the distal end of the insertion sheath." Further, claim 48 recites, *inter alia*, "a distal end where a first distal hole and an over insertion hole are located; an insertion sheath, wherein the over insertion hole is located in the insertion sheath" and "a dilator sized to fit inside the insertion sheath, the dilator having a distal end

positionable distally beyond a distal end of the insertion sheath, wherein the first distal hole is located in the distal end of the dilator.”

Ginn, in contrast, clearly fails to disclose, teach, or suggest each and every element recited in independent claims 1, 28, 45, 46, 47, and 48. For example, at the very least, Ginn fails to disclose, teach, or suggest a “dilator having a distal end positionable distally beyond a distal end of the insertion sheath” and “a first distal hole located in the distal end of the dilator.” Instead, Ginn merely discloses distal openings (e.g., distal openings 249 and 253) that are in a portion of obturator 214 that is within sheath 212.

For example, Ginn clearly discloses a “sheath 212 [that] includes first and second sets of side ports 242, 250” and an “obturator 214 [that] includes … first and second sets of distal openings 249, 253.” Col. 8, lines 15-16 and lines 40-43; *see also* FIG. 11. Ginn further explains that “when the obturator 214 is fully received in the sheath 212 … the first and second sets of distal openings 249, 253 are axially aligned with the first and second sets of side ports 242, 250, respectively.” Col. 8, lines 43-48. As is clear from these passages, neither distal opening 249 nor distal opening 253 in Ginn is located in a distal end of a dilator positionable distally beyond a distal end of an insertion sheath.

Accordingly, because Ginn fails to disclose, teach or suggest each and every limitation of independent claims 1, 28, 45, 46, 47, and 48, a *prima facie* anticipation rejection has not been established. *See, e.g., Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987) (“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference”); *see also Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1566

(Fed. Cir. 1989) ("The identical invention must be shown in as complete detail as is contained in the . . . claim.").

Kensey also clearly fails to disclose, teach, or suggest each and every element recited in independent claim 48. For example, at the very least, Kensey fails to disclose, teach, or suggest "a distal end where a first distal hole and an over insertion hole are located; an insertion sheath, wherein the over insertion hole is located in the insertion sheath" and "a dilator sized to fit inside the insertion sheath, the dilator having a distal end positionable distally beyond a distal end of the insertion sheath, wherein the first distal hole is located in the distal end of the dilator."

Accordingly, because Kensey fails to disclose, teach or suggest each and every limitation of independent claim 48, a *prima facie* anticipation rejection has not been established. *See, e.g., Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987) ("A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference"); *see also Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1566 (Fed. Cir. 1989) ("The identical invention must be shown in as complete detail as is contained in the . . . claim.").

Moreover, aside from the novel limitations recited therein, claims 4, 5, 7, 12-16, 20-22, 24, 25, 29-39, and 49-60 are also allowable at least by virtue of their dependency upon allowable base claims 1, 28, 45, 46, 47, and 48. Applicants respectfully request, therefore, that the rejection of claims 4, 5, 7, 12-16, 20-22, 24, 25, 29-39, and 49-60 under 35 U.S.C. § 102 be withdrawn, and these claims be allowed.

Conclusion

For at least the foregoing reasons, Applicants believe that each of the presently pending claims in this application is in immediate condition for allowance. Accordingly, Applicants respectfully request a favorable action on the merits. If the Examiner has any further comments or suggestions, Applicants invite the Examiner to telephone the undersigned attorney to expedite the handling of this matter.

Respectfully submitted,

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